

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 1:13-md-2419-FDS

This Document Relates to:
All Cases

[Plaintiffs' Steering Committee's Proposed] MDL Order No. __

August __, 2013

[The Plaintiffs' Steering Committee conferred with the Creditors' Committee and the Chapter 11 Trustee on this proposed mediation order, and resolved 90% of all substantive disagreements. This proposed order shows, in redline, proposed changes to the draft mediation order filed by the Creditors' Committee and the Chapter 11 Trustee earlier this evening. The Plaintiffs' Steering Committee will address the areas of disagreement at the August 9, 2013 status conference and/or in a pleading filed before the status conference.]

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MDL Procedural Order Relating to NECC Mediation Program

By this order, the Court approves, so-orders and implements, to the fullest extent of its authority and jurisdiction, the NECC Mediation Program attached hereto as Exhibit A.

IT IS SO ORDERED.

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The Honorable F. Dennis Saylor IV
United States District Judge

Dated: _____, 2013

**UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION**

In re:

NEW ENGLAND COMPOUNDING
PHARMACY, INC.,

Debtor.

Chapter 11

Case No. 12-19882-HJB

Procedural Order Relating to NECC Mediation Program

By this order, the Court approves, so-orders and implements, to the fullest extent of its authority and jurisdiction, the NECC Mediation Program attached hereto as Exhibit A.

IT IS SO ORDERED.

Dated: _____, 2013
Springfield, Massachusetts

The Honorable Henry J. Boroff
UNITED STATES BANKRUPTCY JUDGE

EXHIBIT A

NECC Mediation Program Order

WHEREAS, the chapter 11 trustee (the “Trustee”) appointed in the chapter 11 bankruptcy (the “NECC Bankruptcy Case”) of New England Compounding Pharmacy, Inc. (“NECC”),¹ in conjunction with the Official Committee of Unsecured Creditors (the “Official Committee”) appointed in NECC’s Bankruptcy Case, pursuant to their respective authority and duties under the Bankruptcy Code to develop a chapter 11 plan (“Trustee’s Plan”), and together with the Plaintiffs’ Steering Committee (the “PSC”) appointed in In re New England Compounding Pharmacy Cases Litigation, Case No. 13-cv-02419 (the “NECC MDL Proceeding”) pending before the United States District for the District of Massachusetts (the “MDL Court”),² (the Trustee, Official Committee, and PSC, collectively, the “Interested Parties”), desire to establish and conduct a mediation program (the “NECC Mediation Program”).

WHEREAS the goal of the NECC Mediation Program is to globally resolve the claims of those parties (hereinafter, the “Unaffiliated Non-Debtor Claimants”) (i) who are non-debtors and who are not NECC Affiliated Defendants as referenced in MDL Order No. 6 in NECC MDL Proceeding; (ii) who have or may have claims asserted against them as defendants by personal injury tort and wrongful death plaintiffs (the “Plaintiff Claimants”) which arise out of or relate to NECC products; and (iii) who, as a result of claims or potential claims against them by Plaintiff Claimants, may have or assert potential indemnification, contribution, reimbursement or other

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¹ The NECC Bankruptcy Case is pending before Judge Boroff in the United States Bankruptcy Court for the District of Massachusetts (the “Bankruptcy Court”), case captioned *In re New England Compounding Pharmacy, Inc.*, Ch. 11 Case No. 12-19882.

² The actions assigned to MDL 2419 are collectively referred to herein as the “NECC MDL Cases.”

claims against the NECC estate (the “Unaffiliated Non-Debtor Liability Claims”) that are based upon or relate to the Plaintiff Claimants’ claims;

WHEREAS, the procedures set forth will facilitate Unaffiliated Non-Debtor Claimants’ participation in the NECC Mediation Program, possibly avoid unnecessary and costly and protracted litigation, and conserve limited resources;

WHEREAS, preclusion of discovery during mediation could impact or impair the Plaintiff Claimants’ ability to gather information necessary to comply with state law requirements applicable to claims against health care providers, including but not limited to pre-suit notice, affidavit or certification of merit, and/or panel or arbitration review requirements (“State Law HCP Suit Requirements”);

WHEREAS, the exceptional circumstances presented by the NECC Bankruptcy Case and the NECC MDL Proceeding and the interests of NECC’s creditors in an expedited resolution of the NECC Bankruptcy Case and the distribution of available funds to NECC’s creditors warrant early, good faith mediation efforts towards negotiating a global or near global resolution under the Trustee’s Plan;

WHEREAS, Paragraph II.J of MDL Order No. 6, *inter alia*, (i) directs the Trustee, the Official Committee and the PSC “to confer and submit to the [MDL] Court within 30 days a proposed mediation order to be entered in [the MDL] Court and the Bankruptcy Court concerning all unaffiliated defendants and non-parties” and further provides as follows:

“The Proposed Mediation Order shall provide that any unaffiliated defendant or non-party who elects to participate in mediation shall, among other things:

1. be exempt from discovery except as required to facilitate participation in mediation. The exemption should continue in force so as long as the mediator does not report to this Court and the Bankruptcy Court that (a) the subject defendant or potentially responsible party is not negotiating in good faith; (b) that the mediation as to the defendant or potentially responsible party has

- reached impasse terminating mediation as to them; or (c) that the mediation as a whole has reached impasse and should be terminated. The election shall require the defendant or potentially responsible entity/person to submit to jurisdiction of this Court and Bankruptcy Court;
2. voluntarily agree to a standing injunction order tolling any statutes of limitation or other applicable time bar statutes;
 3. voluntarily agree to a standing injunction order suspending or extending any and all applicable pre-suit or post-suit requirements related to health care orders, including any notices, arbitration or panel submission requirements, or affidavits of service;
 4. provide a statement to the appointed mediator, the Plaintiffs' Lead Counsel, a liaison to the defendants, the trustee, and the Creditors' Committee identifying any other potentially responsible parties liable to tort claimants or liable to the defendants or another potentially responsible party regarding injuries related to the allegedly contaminated methylprednisolone acetate and the grounds or basis of the claim. Statements should be deemed mediation material and not admissions, and are not admissible in any judicial proceeding; and
 5. file a proof of claim in the Chapter 11 Case."

WHEREAS, orders implementing the NECC Mediation Program must be entered in the

Bankruptcy Court ~~and~~ in the MDL Court, as the MDL Court has jurisdiction over NECC MDL

Cases and liquidation of personal injury and wrongful death cases involved in the NECC

Bankruptcy Case and may enforce and facilitate portions of this order applicable to those cases.

NOW, THEREFORE, the NECC Mediation Program is established as follows:

1. The Interested Parties, together with any Unaffiliated Non-Debtor Claimants who notify the Interested Parties by a date (such date, the "Opt-in Date") that is thirty (30) days after the first entry of this Order by the MDL Court or the Bankruptcy Court that they wish to participate in the mediation and the mediator selection process ("Interested Unaffiliated Non-Debtor Claimants"), shall meet and confer in good faith to agree upon a national mediator ("Mediator"), subject to approval and appointment by the Bankruptcy Court. The Interested Unaffiliated Non-Debtor Claimants shall promptly meet, organize themselves and appoint a self-

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governed liaison committee (the “NDC Mediation Committee”) of no more than seven members for the purpose of facilitating the mediator selection process and mediation logistical issues, as well as such other organization, management liaison functions the Interested Unaffiliated Non-Debtor Claimants agree upon. The NDC Mediation Committee need not be appointed or approved by any court and is solely constituted for the purposes described herein. The Interested Unaffiliated Non-Debtor Claimants shall provide a list of the members of the NDC Mediation Committee to the Interested Parties no later than seven (7) days after the Opt-In Date. The Interested Parties and NDC Mediation Committee shall negotiate in good faith their respective responsibilities for the fees and related costs of the mediator’s services and shall consider whether a cap on such fees is appropriate. The Interested Parties and NDC Mediation Committee shall submit their joint proposal to the MDL Court for a Mediator and a proposal for a fee sharing structure no later than fourteen (14) days after the Opt-In Date. If the Interested Parties and NDC Mediation Committee have not agreed as to a mediator as of that date, any of the Interested Parties and Interested Unaffiliated Non-Debtor Claimants may submit a proposal to the MDL Court regarding the appointment of a mediator no later than eighteen (18) days after the Opt-In Date. All defendants and known potentially responsible parties shall thereafter be notified of the choice of mediator within ten (10) days of the Court’s order with respect to the selection of a mediator.

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2. While the parties contemplate that the mediation efforts will be largely self-executing in the sense that these will be private mediations that do not require active court supervision or intervention, some administrative and substantive court actions might be required.

The MDL Court shall have jurisdiction over all aspects of the NECC Mediation Program, except as specifically delegated by the MDL Court. The Interested Parties and the NDC Mediation

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Committee shall meet and confer within 30 days of the Opt-In Date regarding the appropriate

procedures that will govern discovery disputes within the mediation, including (i) whether ~~to~~
~~recommend to the MDL Court that~~ the mediator ~~or the Magistrate Court~~, be given special
~~“Discovery Master” status for purposes of the mediation program.~~

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3. To the extent preservation or *de bene esse* discovery, including depositions, are reasonably necessary, the involved parties by agreement or by leave of the ~~Discovery Master~~ or by Order of the ~~MDL~~ Court may take such discovery. Additionally, application for relief on shortened notice in such situations may be made to the ~~Discovery Master or MDL~~ Court if exceptional circumstances warrant.

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4. In order to participate in the NECC Mediation Program, eligible entities or individuals must provide the following informal discovery to the Trustee, the Official Committee and PSC by the deadlines and in the manner established by the Mediator:

a. AS TO CLINIC, HEALTH CARE PROVIDER, AND HOSPITAL PARTICIPANTS ONLY:

- (1) A copy of the list, required by the Bankruptcy Court to be provided to the Trustee, of all patients reasonably known or available to whom the participant administered methylprednisolone acetate that came, or likely came, from one of the following three lots produced by NECC: 05212012@68, 06292012@26, and 08102012@51 (the “Lots”); such patient list shall be kept confidential in accordance with the Bankruptcy Court’s order.
- (2) A statement fully identifying the entity(ies) or person(s) from whom such Lots were purchased or obtained.

b. AS TO ALL DEFENDANTS AND POTENTIALLY RESPONSIBLE PARTY PARTICIPANTS:

- (1) Any and all policies of insurance, including without limitation of the foregoing, professional liability, general liability, and comprehensive or umbrella policies, issued to the clinic or healthcare provider and/or its principal officers and directors, for the policy periods including calendar years 2012 and 2013.
- (2) Any documents relating to any reservation of rights or rejection or limitation of insurance coverage relating to the claims related to or arising out of the purchase or administration of the Lots.

(3) Any and all agreements covering calendar year 2012 whereby the participant agreed to indemnify another party (or required another party to indemnify it) in connection with the claims related to or arising out of the purchase or administration of the Lots.

(4) A list of all potentially responsible parties liable to tort claimants or liable to the defendants or another potentially responsible party regarding injuries related to the allegedly contaminated methylprednisolone acetate and the grounds or basis of the claim.

(5) All documents responsive to subpoenas previously served by the PSC and to which no timely objection was filed or, if filed, which has been withdrawn.

c. The Discovery Master shall determine what additional information and documents the parties shall provide or exchange in order to facilitate a mediated

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settlement or resolution and the timing and manner of the production. The

~~Discovery Master~~ may in his or her discretion allow examinations under oath

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under such terms, limits and conditions as he or she may prescribe and which may be conducted in deposition format pursuant to the Federal Rules of Procedure or equivalent Bankruptcy Rule.

- d. The MDL Court's HIPAA and information protective orders shall govern and be applicable to NECC Mediation Program's participants. Any party producing discovery within the NECC Mediation Program may designate such discovery as confidential pursuant to such protective order.

- e. All such documents produced or exchanged in connection within the Mediation shall be deemed confidential for purposes of Mediation, and shall not be admissible in any later proceeding except to the extent necessary to address the sufficiency of such production, or relating to failure to mediate in good faith.

Such documents, if filed with the ~~Court~~, shall be filed under seal. No parties

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participating in the NECC Mediation Program shall disclose information obtained in the NECC Mediation Program to anyone other than other participants in the NECC Mediation Program (including the mediator) and the Bankruptcy Court or MDL Court. All documents supplied by any participant during the mediation process will be returned in the event the mediation process is not successful with no copy of any such document being retained by any other party. The relevant parties may mutually agree, however, to retain documents that ordinarily would be produced or obtained during discovery and are encouraged to so agree to minimize costs.

5. Any of the following parties may choose to participate in the NECC Mediation Program by filing a NECC Mediation Program Participation Notice and Agreement in the MDL Court (a “Participation Notice”). The form of Participation Notice is attached as Appendix A).

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- a. Any party named as a defendant or third party defendant in any case presently pending in the NECC MDL Proceeding or in any other state or federal court (the “Defendants”);
- b. Any other party with potential liability for claims related to or arising out of the purchase or administration of NECC products, whether or not involved in any current litigation or alternative dispute resolution (“Potentially Responsible Parties”, who, together with the Defendants, comprise the Unaffiliated Non-Debtor Claimants); and
- c. Any employee, officer, director, agent, partner, shareholder, guarantor, indemnitor, affiliate or subsidiary of a Defendant or Potentially Responsible Party (“Unaffiliated Non-Debtor Claimant Affiliates”) who has potential direct or secondary liability in connection with NECC; provided that, in the alternative to filing a Participation Notice, such Unaffiliated Non-Debtor Claimant Affiliate may join in a Participation Notice filed by an Unaffiliated Non-Debtor Claimant by identifying themselves and co-executing the Participation Notice.
- d. By agreeing to participate in the NECC Mediation Program, a party does not admit in any way that it has actual or potential liability to any other party, and the use of the term “potential liability” in paragraphs b and c above shall not be construed as an admission by any party.

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6. A Participation Notice must be executed and mailed to counsel to the Official Committee, Lead Counsel for the PSC, at the following addresses:

a. **To the Trustee:**

Paul D. Moore, Esq.
Duane Morris, LLP
Suite 2400
100 High Street
Boston, MA 02110
pdmoore@duanemorris.com

b. **To counsel for the Committee:**

William R. Baldiga Esq.
Brown Rudnick LLP
One Financial Center
Boston MA 02111
E-mail: Wbaldiga@brownrudnick.com

c. **To Lead Counsel for the PSC:**

Thomas M. Sobol Esq.
Hagens Berman Sobol Shapiro LLP
55 Cambridge Parkway, Suite 301
Cambridge MA 02142
E-mail: tom@hbsslaw.com

7. A Participation Notice shall be effective on and as of the date it is executed (the “Effective Date”). By executing a Participation Notice, an Unaffiliated Non-Debtor Claimant and Unaffiliated Non-Debtor Claimant Affiliate shall irrevocably be deemed to submit to the jurisdiction of the MDL Court for all issues or matters relating to the interpretation and enforcement of this Order.

8. Upon the Effective Date of a Participation Notice, and based upon the voluntary consent provisions contained in the Participation Notice:

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a. **Bankruptcy Court Proof of Claim.** Any Unaffiliated Non-Debtor Claimant or Unaffiliated Non-Debtor Claimant Affiliate executing a Participation Notice shall, if it has not already done so, file a proof of claim with the Bankruptcy Court in the NECC Bankruptcy Case within ten (10) days of the Effective Date of the Participation Notice.

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b. **MDL Discovery Stay.** Any person, organization, or entity executing a Participation Notice shall not be subject to general discovery in the NECC MDL Cases except for special discovery situations referred to Paragraph 2 above. Thus, all discovery in the NECC MDL Cases is stayed as to such enrolled participants until further order of MDL Court. As a result of mediation participants filing a proof of claim in the NECC Bankruptcy Case, it is expected that any state court cases in which they are parties will be transferred to the MDL Court such that discovery will be stayed in those cases as well. Nothing in this paragraph shall affect the Mediator's powers provided herein this Order. Nor shall anything in this paragraph prohibit parties from voluntarily providing documents responsive to subpoenas previously served by the PSC (and as modified by agreement or by the MDL Court).

c. **Time Bar Tolling Order.** Any person, organization, or entity executing a Participation Notice, together with their respective heirs, successors, assigns, personal representatives, or bankruptcy trustees, general partners, and joint venture partners agree and warrant that, with respect to civil liability claims of any source or under any jurisdiction, that are based upon, arising out of or relating to persons or Estate of any deceased person claiming they (or a person upon

which they are derivatively claiming) were administered allegedly defective or contaminated NECC products, the running of time under any statute of limitations or repose or by way of estoppel, laches or any other time-related defense shall be tolled and suspended from the “Effective Date” of their Participation Notice until further Order of the Bankruptcy Court or the MDL Court (the “Tolling Period”). Each person, organization, or entity executing a Participation Notice agrees and warrants that, should time-related defenses apply, the time elapsed during the Tolling Period shall not be used in the calculation of any time-related defense, including but not limited to, any statute of limitations or repose, laches or estoppel or State Law HCP Suit Requirements which would otherwise arise during such Tolling Period. It is understood that by filing a Participation Notice or by deferring filing any suit in reliance on this tolling order, no party is waiving any claims or time-related defenses that may have accrued up to the Effective Date of the Participation Notice. This agreement shall not be construed as a tolling or waiver of any claim or time-related defense that has arisen as of the Effective Date or which may arise after the date of termination of Tolling Period, excluding the period during which this provision has operated to toll any time-related defense. The Bankruptcy Court or the MDL Court, each to the extent of its jurisdiction, may set the start of time bar resumption dates based upon equitable circumstances, including maintaining in force the Tolling Period in order to afford parties reasonable discovery to frame and assert complaints, claims, cross-claims, third-party claims or affirmative defenses.

d. Waiver or Stay of Proceedings; Stay and Extension of State Law HCP Suit

Requirements. In order to protect the interests of parties affected by stays in this case, including the discovery stay described in paragraph 7.b. hereof, with respect to civil liability claims against health care providers filing a Participation Notice any and all State Law HCP Suit Requirements in any lawsuit, case or claim, whether filed or not, asserting or based upon Unaffiliated Non-Debtor Liability Claims are hereby deemed VOLUNTARILY WAIVED, STAYED or EXTENDED, as the case may require, until further order of the MDL Court or the Bankruptcy Court. Each person, organization, or entity executing a Participation Notice agrees and warrants that time elapsed during the period the stay/extension is in force shall not be used in the calculation of due or action dates prescribed in any State Law HCP Suit Requirements, including but not limited to the time to file, serve, obtain or present any pre-suit notice, any affidavit or certification of merit, or any request for panel review or arbitration requirement. The Bankruptcy Court or the MDL Court, each to the extent of its jurisdiction, may set the restarting of due or action dates prescribed in any State Law HCP Suit Requirements based upon equitable circumstances, including maintaining in force the stay/enlargement to afford parties reasonable time and discovery to comply with a State Law HCP Suit Requirement.

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e. All lists provided pursuant to Paragraph 4(b)(4) relating to potentially responsible parties and allegations asserted by the participating party shall not be expanded should the mediation not be successful in achieving a settlement or resolution

with the party submitting it as to all claims related to or arising out of the purchase or administration of recalled NECC products.

9. This NECC Mediation Program, including the form of Participation Notice, shall be filed on the docket of the Bankruptcy Court and MDL Court. A copy of this NECC Mediation Program and the form of Participation Notice shall also be posted on the Trustee's website for NECC. To the extent any of the following (or their counsel) do not otherwise receive them electronically from ~~the MDL~~ Court or the Bankruptcy Court, the Trustee shall promptly provide written notice of this NECC Mediation Program and form of Participation Notice to (i) those customers of NECC who received products from the Lots; (ii) all known Defendants (other than Affiliated Defendants) in actions related to or arising out of the purchase or administration of the Lots; and (iii) any party (or its representative) who the Trustee learns may qualify for participation in the NECC Mediation Program, including parties identified as Potentially Responsible Parties during the proof of claim process in the NECC Bankruptcy Case.

10. The Official Committee and the PSC shall be responsible for maintaining a list all Unaffiliated Non-Debtor Claimants with active submitted Participation Notices, and for providing it to the Trustee on a current basis. If, for any reason, the Trustee, the Official Committee or the PSC deem it necessary to file the list of Unaffiliated Non-Debtor Claimants to the Bankruptcy Court or the MDL Court, or to identify any of the participants, they shall do so under seal.

11. The active mediation process shall continue until (a) the mediator declares an impasse as to a participant, in which case the mediation and MDL Discovery Stay shall end either as to that participant only, or as to the NECC Mediation Program as a whole (in which

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latter case the NECC Mediation Program and MDL Discovery Stay shall end as to all parties); or

(b) ordered terminated in whole or part by the ~~MDL~~ Court *sua sponte* or upon application of any party showing good cause for the termination. The Mediation Program is voluntary and any person or entity may withdraw on notice to the mediator, upon which the terms of this Mediation Program shall cease to apply to that person or entity, including without limitation the stay of discovery against any such person or entity. If directed by either the Bankruptcy Court or the MDL Court, any party so directed shall provide a status or progress report to such court (in such detail and in such time frame as the directing court requires).

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12. The schedule, location and time of each mediation session shall be either (i) established by the mediator, subject to the advice and consent of the Interested Parties and other Participants, or (ii) should there be any conflict as to any of the foregoing not amenable to resolution by the Mediator, subject to the Final Order of ~~MDL~~ Court

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13. The Mediator may require, in anticipation of any mediation session, production of such documents or position papers (briefs) as s/he may reasonably require subject to such schedule for production as s/he may establish from time to time.

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14. *Ex parte* communication with the Mediator is not proscribed; in fact, it is encouraged as a means to convey to the Mediator, subject to such further disclosure as the mediator and the communicating party may agree upon, settlement positions, factual or legal arguments, etc.

15. All parties to the mediation agree to mediate in good faith.

16. Upon approval of this NECC Mediation Program by the MDL Court, the ~~MDL~~ Court may modify the terms of the NECC Mediation Program as it deems necessary or appropriate to facilitate the mediation process contemplated hereby.

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